



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/533,827

05/03/2005

Michael Birsha Davies

P33145USW

4175

23347

7590

05/24/2007

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B475

FIVE MOORE DR., PO BOX 13398

RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,827

Applicant(s)

DAVIES ET AL.

Examiner

Annette F. Dixon

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/3/05.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-21 and 23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Rand et al. (WO 98/56444).

As to Claim 1, Rand discloses a holder for dispensing a dispensing container system (the combination of elements 2 and 8) which is adapted to dispense a quantity of a fluid contained therein on movement thereof relative to the holder and further includes a dispensing counter means (13) for counting the number of quantities of the fluid dispensed, the holder having a molded plastic body (1) with inner and outer surfaces, the inner surface bounding a cavity adapted to receive the dispensing container system (the combination of elements 2 and 8) and the body (1) to advance the dispensing counter means to indicate the dispensing of a quantity of the fluid, wherein the body (1) is formed with an outlet port in communication with the cavity such that the fluid dispensed from the dispensing container system (the combination of elements 2 and 8) is dischargeable there through, and wherein an aperture (20) extends through the body from the outer surface to the inner surface in alignment with the counter advance means (17). (Figure 2).

As to Claims 2-4, 11, 15, 19-21, 24, and 30, Rand discloses the recited particulars of the counter and advance means, wherein the counter (13) and the ratchet elements of the advance means (17) are utilized to actuate the medicament to the patient and advise the patient of the amount of medicament remaining. (Figure 2).

As to Claims 5-10, 12, and 23, Rand discloses the recited orientation of the dispensing container system (the combination of elements 2 and 8) to prevent unwanted rotations. (Figure 2).

As to Claims 13, 14, and 16-18, Rand discloses the outlet port of the holder forms a nozzle for insertion into the nose of a patient (Page 8, Lines 8-11).

As to Claims 25-29, 31, and 32, Rand discloses the container (2) has an outlet member (6) and a container member (the region holding the medicament) which contains the fluid and is movable relative to the outlet member to dispense fluid from the outlet member. Further Rand discloses the use of stand (10) to support the container (2) in operation.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3771

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al. (WO 98/56444).

As to Claims 22 and 33, Rand disclose a holder for an inhaler comprising all the recited elements, yet does not expressly disclose the use of injection molding. However, at the time the invention was made the use of injection molding in the formation of inhalers was well known for the ability to enable the uniform construction of the device thereby lowering the costs associated with manufacture. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the holder for the inhaler via injection molding as this process enabling higher product production as the Applicant has done.

6. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al. (WO 98/56444) in view of Keane et al (WO 02/00281).

As to Claims 34 and 35, Rand discloses a holder for an inhaler comprising all the recited elements, yet does not expressly disclose the use of a separate outer cover to protect the holder assembly. However, at the time the invention was made the use of

Art Unit: 3771

an outer cover to protect the holder assembly was well known. Specifically, Keane discloses a mouthpiece cap (28) and an exterior housing (the combination of elements 26 and 20) utilized to prevent contaminants from entering the mouthpiece and an exterior housing to provide a supportive environment to the holder against drops and damage (Figures 1 and 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rand to include the outer cover, as taught by Keane to protect the holder device and medicament of the inhaler.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Blacker (6,142,339) and O'Leary (6,701,917)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Annette F Dixon
Examiner
Art Unit 3771



JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

5/23/07